

LONG TERM USE OF THE SDM FOLLOWING THE EFFICACY STUDY

Final Report



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Executive summary

At the conclusion of the one-year efficacy study of the Standard Days Method (SDM) participants were invited to participate in additional two years of follow up. The purpose of the long-term follow-up study was to examine long-term efficacy and continuation of the method, and determine if cycles out of the 26-32 day range continue to be an important reason for method discontinuation.

Some 197 women in Bolivia, Peru, and the Philippines participated in the long-term follow-up study. They were followed for two years, and interviewed at 3, 6, 12, 18, and 25 months. At each interview they were administered a standard follow-up form to determine if they were still using the SDM, and elicit information about satisfaction with the method and any problems with method use. The interviews were administered by the same providers who counseled the women in method use at the beginning of the SDM efficacy.

Only 14 participants reported that they became pregnant while using the SDM in the second and third years of use. Life tables were calculated to establish long-term failure rates of the SDM. The typical use pregnancy rate for year 2 was 5.2; for year 3 it was 3.4. These results show that the method continues to be effective for long term users.

Of the 197 participants, 67% were still using the method two years later. This continuation rate is particularly high given that fertility preferences were not a condition for participation in the study. Only seven women reported that they had two cycles out of the 26-32 day range in a year, suggesting that cycle irregularity is not a problem for women who completed the first year of method use with no more than one cycle out of range. Women who complete the first year of SDM use are likely to continue to be able to use the method successfully and effectively.

ABBREVIATIONS AND ACRONYMS

IRH	Institute for Reproductive Health
SDM	Standard Days Method
STI	Sexually Transmitted Infection

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I. Background

The SDM® (SDM) is a fertility awareness-based method of family planning that identifies days 8-19 as the fertile window for all users in all cycles. Users who wish to prevent pregnancy avoid unprotected intercourse on those days (arévalo et al., 1999). The method is most effective for women with cycles that usually range 26-32 days (Sinai et al., 2004). It is often used with CycleBeads™, a string of color coded beads that help women keep track of the length of their cycle and of their cycle days.

A multisite clinical trial of the SDM followed women in Bolivia, Peru, and the Philippines for up to 13 cycles of method use. Results showed the method to be effective and acceptable. The failure rate was 4.8 with correct use and 12.0 when all pregnancies and cycles were included in the analysis., including cycles in which the couple had unprotected intercourse during the days the method identified as fertile (Arévalo et al., 2002).

In the efficacy trial of the SDM the main reason for method discontinuation was irregular cycles. Some 28% of participants were removed from the study for that reason. Only 8% of study participants stopped using the method because they or their partner did not like or trust the method, or for other voluntary reasons. Other participants left the study because they became pregnant (9%), decided to get pregnant (2%), were no longer exposed to the risk of pregnancy because of marital dissolution (1%) or were lost to follow up (7%). At the end of the on-year efficacy study 46% of participants were still using the method. Clearly, then, the method is very acceptable to users and their partners, and the continuation rate is high for women with more regular cycles. It is important, therefore, to determine if cycle regularity continues to be an issue in the second and third year of method use.

The present study followed efficacy-study participants for two additional years. The purpose of the study was to examine long-term efficacy and continuation of the method, and determine if cycles out of the 26-32 day range continue to be an important reason for method discontinuation. The study was useful because this is a new method. Programs wishing to add the SDM to the contraceptive choices they offer need to weigh the cost of integrating and offering a new method against the benefit of coverage it offers. Long term efficacy and continuation are important information in this equation, especially given the SDM's requirement for cycle regularity.

The study was designed to answer the following questions:

- What is the long-term continuation rates of SDM use?
- What is the long-term effectiveness of the SDM?
- How many women stop using the SDM because of cycle irregularity?
- Do women continue using the SDM as they were initially counseled?
- Why do women stop using the SDM?

II. Methodology

The efficacy trial of the SDM followed 478 women in five economically and culturally diverse sites in Bolivia, Peru, and the Philippines for up to 13 cycles of method use. Participants in the efficacy trial had to meet the following criteria:

- Age 18 to 39 at the time of admission into the efficacy trial,
- No use of hormonal contraceptives in the three months prior to enrollment,
- Neither the woman nor her partner were sterilized,
- Met the cycle regularity criteria, as established using a string of specific questions,
- Male partner agreed to women's participation in the efficacy trial,
- No history of infertility,
- Not at high risk for STIs,
- Sexually active,
- Wished to avoid pregnancy for at least one year.

Breastfeeding women were admitted to the efficacy trial only if they met all the above criteria, including having regular cycles during the three months prior to enrolling in the trial.

During their participation in the efficacy trial women were interviewed monthly, and completed coital logs daily. At the end of the efficacy study the 214 women who successfully completed 13 cycles of method use were invited to participate in the long-term follow-up study. A total of 197 women agreed to participate. They were followed for up to two additional years, and interviewed at 3, 6, 12, 18, and 24 months after starting their participation in the long-term follow-up phase of the study. Participants did not complete coital logs, and were not asked whether they still wished to avoid pregnancy in the near future. All couples who successfully completed the efficacy study were eligible to be admitted to the long-term follow-up study, regardless of their fertility preferences. The following table shows the differences between the two studies – the efficacy study (the first year of method use), and the long-term study which followed it and is the focus of this report.

Table 2.1: Differences between the efficacy study and the long-term follow-up study

	Efficacy study	Long-term follow-up study
Number of participants at admission	478	197
Length of study	1 year	2 years
Frequency of interviews	Monthly	At 3, 6, 12, 18, 24 months
Use of coital logs	Yes	No
Use of pregnancy tests	Yes	No
Wish to avoid pregnancy at least 1 year	Yes	Not necessarily

In each long-term follow-up interview participants were administered a standard follow-up questionnaire to determine if they were still using the SDM, and elicit information about satisfaction with the method and any problems with method use. If the participant self-reported that she was pregnant, she was administered a pregnancy questionnaire to determine if the

pregnancy was planned (if she had stopped using the SDM in advance of the pregnancy) or unplanned, and to establish how many months the woman contributed to the study before she became pregnant (or stopped using the method in order to become pregnant). If the woman reported that she had stopped using the method during the interval between interviews, she was administered an exit questionnaire to determine the reason for discontinuation, and how many cycles the woman contributed to the study before she stopped using the method. If the interviewer was not able to locate a participant after three attempts, or if she participants and has moved to an inaccessible location, the lost-to-follow-up form was completed.

These interviews were administered by the same providers who counseled the women in method use a year earlier, and administered the monthly follow-up interviews during the efficacy trial. IRH staff, in conjunction with the local principal investigators, conducted retraining session for the providers. During this training session they were instructed in the protocol for the long-term follow-up study, and were familiarized with the study instruments. The new instruments were much briefer than those used in the efficacy trial, but dealt with similar issues, so were easy for providers to learn and understand. The retraining included also discussion of informed consent issues.

Life-tables were calculated in the efficacy study to establish failure rates. Women were interviewed every cycle; we calculated survival per cycle; pregnancies were determined by pregnancy test; we knew exactly when women became pregnant, left the study, or were lost to follow-up; and women who had a second cycle out of the 26-32 day range were removed from the study.

Life-tables were calculated also in the long-term follow-up study. However we expect that results are less accurate, because women were interviewed periodically and we rely on their recollection to determine in which cycle they became pregnant. Also, pregnancy was self reported. It is possible that some women who became pregnant did not report it. Interviewers asked participants in each interview if they had cycles out of the 26-32 day range, and reminded participants that if they have a second such cycle in a year the method may not be as effective for them. However, because participants did not use coital logs we have no way of knowing their exact cycle length, and if they followed this recommendation.

With these drawbacks in mind, life-tables were calculated to determine second and third year (unplanned) pregnancy rates. Participants in the long-term study did not complete a coital log, and were not asked whether they did or did not have unprotected intercourse during the days the method identifies as fertile. Therefore we could not calculate correct use failure rates. The rates we present here are typical use failure rates.

Use of the SDM requires either abstinence during the fertile days or use of a barrier method as backup on these days. However, to facilitate the study of method efficacy participants in the efficacy study were asked to abstain on days 8-19 of the cycle, but to report in their coital log if they had intercourse on the fertile days, with or without a back-up method. This requirement was lifted when participants moved on to the long-term follow-up study. The typical use rate reported here, therefore, more closely reflects real-life (not study setting) use of the method

III. Results

Participants in the long-term follow-up study represented a mix of socio-demographic characteristics. They resided in urban, mixed urban/rural, and rural sites. More than 90% had completed primary education and most were literate. Almost all participants had children, with at least one child younger than two years old when admitted to the efficacy study.

III.1 Efficacy and correct use

Of the initial 197 participants, only 14 women reported that they became pregnant while using the SDM in the second and third years of use. We do not know if they used the method correctly in the pregnancy cycle, or if they had unprotected intercourse during the fertile days. This translates into very high typical use efficacy rate, as seen in the following Table. The Table shows pregnancy rates for typical use of the SDM in the first, second, and third years of use.

Table 3.1: Typical use life table pregnancy rates

Period	Pregnancy rate	95% confidence interval
Year 1 (from the efficacy study)	11.96	2.33 to 7.11
Year 2	5.24	1.83 to 8.53
Year 3	3.43	0.43 to 6.34

Year 1 rates were calculated per 13 cycles

Years 2 and 3 rates were calculated per 12 calendar months each

As expected, the pregnancy rate for typical use declined with time. It is only 5.2 for the second year of use and 3.4 for the third year, compared to almost 12.0 for the first year of use. It is possible that some women who became pregnant during the long-term follow-up study period did not report the pregnancy to us. It is also possible that women who reported that they stopped using the method some months earlier because they wished to become pregnant were actually using the method until their pregnancy but are not captured here. Therefore these second and third year pregnancy rates are only approximations. Clearly, however, the method continues to be effective for long-term users.

Participants were asked each interview whether they had abstained or used condom or withdrawal during their fertile days in the preceding months. During the efficacy study participants were asked to abstain from sexual intercourse during their fertile days. They reported doing so in 92% of cycles. This was not a requirement for participation in the long-term follow-up study. In the first interview 86.7% reported abstaining (9.9% used condom; 3.5% used withdrawal). In the last interview 83.2% reported abstaining (15.6% used condom; 1.2% used withdrawal). Thus, while most participants continued to abstain from sexual intercourse during the days the method identified as fertile, over time there was a noticeable shift toward condom use on the fertile days.

III.2 Continuation

Of the 197 women who entered the long-term follow-up study 132 (67.0%) were still using the method two years later. This is a very high continuation rate, particularly given that at the beginning of the long-term study period women's fertility preferences for the study period were varied – not all couples wanted to avoid pregnancy for the full study period. The following Table shows reasons for discontinuation.

Table 3.2: Reason for exiting the SDM long-term follow up study (n=197)

Period	Percent of participants
Complete 2 additional years of method use	67.0
Wished to become pregnant	11.8
Had two cycles out of the 26-32 day range in a year	3.6
She or her husband did not like or trust the method	3.0
No longer exposed to the risk of pregnancy	2.0
Lost to follow-up	5.6
Unintended pregnancy	7.1

Some 23 participants stopped using the method stating that they wished to become pregnant. Of these, 10 became pregnant before their next scheduled interview. Several women left the study because they no longer had need for contraception due to marital dissolution or a hysterectomy.

Only six women stopped using the method because they, or their partners, did not like or trust the method. Of these, five went on to use a hormonal contraceptive method; the sixth switched to withdrawal. Only two of these had used a hormonal method at some point in the past, before choosing to use the SDM and participating in the efficacy study. For the other three women the SDM was a bridge between using a traditional method or condom inconsistently, and using a modern hormonal family planning method.

Only seven women (3.6%) reported that they had two cycles out of the 26-32 day range in a year, so that they had to stop using the method. This figure is significantly lower than the 28% of participants who left the efficacy study for this reason. This result suggests that women who have almost all (<2) cycles within the 26-32 day range for a year are likely to continue having cycles within this range afterwards. However, it is possible that more women had two cycles out of range in a year, but did not report this. They continued to use the method and, and the method continued to be effective for them.

Of the seven women who reported two cycles out of range, two continued to use the SDM despite recommendations to switch to another method, and became pregnant; one decided to use no method, two switched to withdrawal, one to consistent use of condoms, and one to oral contraceptives.

IV. Discussion

These findings show that the SDM continues to be a highly effective family planning method in the second and third year of method use. They also suggest that cycle irregularity is not a problem for women who had no more than one cycle out of the 26-32 days range in the first year of method use.

A weakness of the study is the retrospective nature of the interviews. Participants were interviewed at three-month intervals for the first six months and at six-month intervals later in the study, and asked about their use of the method in the preceding months. Another weakness is not using coital logs and pregnancy tests, relying instead of participant's answers about their correct and incorrect use of the method and about their pregnancy status.

Because of these weaknesses we posit that our results are only approximations. It is possible that more women had an unintended pregnancy during the study and did not report it. However the failure rates we present here for typical use are very low. Even if twice the women had become pregnant during the study period, the typical-use pregnancy rate would still be compare favorably to other user-directed

The SDM is an effective and acceptable family planning option. A limitation of the method is the requirement for cycle regularity. The method is most appropriate for women whose cycles usually range 26-32 days. A recent study of the theoretical effectiveness of the method showed that women who would continue using the method after a second cycle out of range in a year would still get some protection from pregnancy while using the SDM, but the method would not be as effective for them.

During the efficacy study some 28% of participants were removed from the study because of cycles out of range. However, only seven women reported two cycles out of range in a year in the second and third years of use. Two of them continued to use the SDM and became pregnant, confirming that the method is less effective for women with less regular cycles.

If indeed only seven women had a second cycle out of the 26-32 day range per year in the second and third years of method use, then women who had regular cycles for a year are very likely to continue having regular cycles. On the other hand, if more study participants had cycles out of range but did not report it and continued to use the method, then the method was still very effective for them, despite their less regular cycles, suggesting that the cycle regularity requirement may be less important for women who have regular cycles for a year.

In conclusion, the SDM is an effective and acceptable fertility awareness-based method of family planning. In recent years it has been introduced successfully in a number of countries, to users of varied education, socio-economic, and cultural backgrounds. Our results suggest that it can be an effective method for long-term users. Women who complete the first year of SDM use are likely to continue to be able to use it successfully and effectively.

V. References

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